Statement by
Sharon Hill Price to the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
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Good morning. My name is Sharon Hill Price and I am the Chief Executive Officer of Copernicus Group Institutional Review Board. I would like to thank the Committee for providing me an opportunity to make a statement and testify today.

An IRB's regulatory mandate is to assure the protection of the rights and welfare of human subjects in clinical trials. In our current system, the IRB's responsibility to protect subjects is shared with the investigators, the institution or sponsor, and the government. An IRB carries out its unique role by reviewing study information provided by the sponsor and its agents, and by investigators engaged to perform the study, and determining whether the research adheres to the ethical principles outlined in the Belmont Report as set forth in federal regulations. As CEO, my responsibilities are to direct the administrative functions at Copernicus, while the separate ethical review function is conducted and controlled by our independent Institutional Review Board. On a personal note, I built this company from the ground up, and I take what happened in Study 3014 very seriously. I have always strived to assure that Copernicus provides high quality ethical review.

In August 2001, Copernicus was contacted by PPD and asked to serve as IRB of record for Study 3014, a clinical trial sponsored by Aventis Pharmaceutical, now known as the Sanofi-Aventis Group. This was a large, multi-center trial conducted over a relatively short duration of approximately 6 months. Copernicus initially reviewed and approved the protocol as well as the consent document that was to be used by investigators during the informed consent process with

study subjects. Additionally, the IRB reviewed information for each of the investigators selected by the sponsor. One of those investigators was Dr. Kirkman-Campbell. Dr. Kirkman-Campbell's submission packet was reviewed and in October 2001 she was granted IRB approval to serve as a Study 3014 investigator.

At a committee hearing last year, Ann Marie Cisneros, a former PPD employee, testified that during a monitoring visit to the Kirkman-Campbell site in February 2002, she had called Copernicus and spoken to the President and informed her of concerns found at the site. Her statement surprised us at Copernicus because no one on our staff was aware of any such call having been received. Furthermore, at the time, our searches of documents did not turn up any evidence of a call from Ms. Cisneros.

However, on the afternoon of Wednesday, January 23, 2008, Copernicus found documentation of an anonymous call being taken by one of our professionals on February 21, 2002. Based upon its content, this memorandum appears to describe the call from Ms. Cisneros. For some reason, and contrary to both procedure and training, this memorandum was not forwarded to a supervisor or to the Institutional Review Board as it should have been at the time. Neither was the document placed in the investigator file as it should have been. We have intensively investigated this matter, but we simply do not have an answer as to why this lapse occurred. Had the Board received the information, as it should have, I am confident that the Board would have investigated the matter and taken the appropriate action. While I cannot speak to the independent decision that would have been made by the Board, this action most likely would have included notifying the FDA regarding concerns about the investigator. This call should have been elevated to the Board. On behalf of my company, I offer an apology for this deviation from our standard operating procedure.

In a recent interview in the Journal of Clinical Research Best Practices, Ms. Cisneros encouraged individuals to reach out to someone if they have concerns about research study conduct. I wholeheartedly agree with this advice. There are a number of options open to individuals faced with similar concerns and the IRB should certainly be one of those options. The IRB is a place where both subjects and members of the research community can turn when issues about how a clinical study is being conducted arise or if unanticipated problems that affect subject safety are suspected.

As additional regulatory guidance has been released, Copernicus has continually reviewed and strengthened its policies and procedures in the six years since Study 3014 has ended. The IRB and professional support staff have been trained on existing policies, including those that govern the handling of unanticipated problems such as the kind that arose in Study 3014 in 2002. Our ongoing process improvement efforts continue to strengthen our ability to recognize and appropriately address serious issues that rise to the level of unanticipated risk to subjects or others.

As part of that effort at strengthening our procedures, and of additional significance, Copernicus was one of the first groups to achieve accreditation of our human research protection program by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In order to attain this voluntary accreditation, Copernicus went through a rigorous self-assessment and peer review process to demonstrate strict practice standards that meet or exceed federal human subject protection requirements. Copernicus was reaccredited this past October.

Copernicus has taken its role as a human subject protection entity seriously for the 12 years since first opening its doors in 1996. Although we sincerely apologize for the call that was not handled as it should have been six years ago, we remain proud of the important role that IRBs play in providing ethical review of clinical research. Again, I appreciate the opportunity to testify today and am prepared to answer any questions that you have.